UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: October 9, 2020

SUBJECT: Efficacy Review for Condor 2,
EPA Reg. No. 4091-21
DP Barcode: 458858
E-submission No. 52962

FROM: Kiran Verma
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Biological and Economic Analysis Division (7503C)
Date Signed: October 9, 2020

THRU: Sophie Nguyen
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Product Science Branch
Antimicrobials Division (7510P)
Date Signed: October 7, 2020

TO: Eric Miederhoff, PM 31/Stacey Grigsby
Regulatory Management Branch I
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APPLICANT: W.M. Barr & Company, Inc.

Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl* dimethyl benzyl ammonium chloride (*50% C14, 40% C12, 10% C16)	0.200%
Octyl decyl dimethyl ammonium chloride	0.150%
Didecyl dimethyl ammonium chloride	0.075%
Dioctyl dimethyl ammonium chloride	0.075%
Other Ingredients	99.500%
Total	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, fungicidal), non-food contact sanitizer, 24 hour residual sanitizer

Requested action(s): Add disinfection claim against additional virus (SARS-CoV-2).

Documents considered in this review:

- Cover letter from applicant to EPA dated 7/24/2020
- Proposed label Version 072420 AMEND
- Data Matrix (EPA Form 8570-35) dated 7/24/2020
- One efficacy study (MRID 51079101)
- Confidential Statement of Formula (EPA Form 8670-4) dated 1/14/2020

II PROPOSED DIRECTIONS FOR USE

TO DISINFECT: Hard, non-porous non-food contact surfaces: Hold container 6”-8” from surface and spray until thoroughly wet.”
For SARS-CoV-2, let stand one minute.

III STUDY SUMMARIES

1.	**MRID**	51079101		
Study Objective		Disinfectant – virucidal		
Testing Lab; Lab Study ID		Microbac Laboratories; 640-105		
Experimental Start Date		05/28/20	**Study Completion Date:**	07/21/20
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)		
Indicator Cell Culture		Vero E6 cells (ATCC CRL-1586)		
Test Method		ASTM E1053-20		
Application Method		2 mL of the product was sprayed from 6-8 inches away using 3 sprays until thoroughly wet.		
Test Substance Preparation	**Name/ID**	Condor 2		
	Lots **☐ 1 ☐ 2 ☒ 3**	KK007-64 (0.446% quaternary ammonia), KK007-65 (0.458% quaternary ammonia), KK007-66 (0.442% quaternary ammonia)		
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Glass carriers, 1 per lot		
Test conditions		Contact time: one minute Temperature: 21°C Relative humidity: 55%		

Neutralizer	MEM + 10% NCS + 0.5% Polysorbate 80 + 0.5% Lecithin + 1% HEPES (2 mL)
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	- The following amendments were made to the protocol: (1) correction of typographical error on Project Sheet 1 related to the organism name, (2) clarification to the project sheet that the carriers were to be sprayed from 6-8 inches using three sprays until thoroughly wet. (3) clarification to the "records to be maintained" section of the protocol, and (4) updates to Health Canada references. - For each of the three lots tested, the neutralizer effectiveness/viral interference control exhibited cytotoxicity at the 10^{-2} and 10^{-3} dilutions (100-fold and 1,000-fold away from the mock inoculum) in each of the 4 wells inoculated. The 10^{-4} dilution exhibited 4/4 wells with positive viral cytopathic effect. - For each of the three lots tested, the cytotoxicity control exhibited cytotoxicity at the 10^{-2} and 10^{-3} dilutions (100-fold and 1,000-fold away from the mock inoculum) in each of the 4 wells inoculated. The 10^{-4} dilution exhibited 0/4 wells with positive viral cytopathic effect.

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot KK007-64	Lot KK007-65	Lot KK007-66	
1 minute, RTU spray, 5% fetal bovine serum						
51079101	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)	10^{-2} to 10^{-3} dilution*	Cytotoxicity	Cytotoxicity	Cytotoxicity	6.60
		10^{-4} to 10^{-7} dilution*	Complete inactivation	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤ 3.10	≤ 3.10	≤ 3.10	
		Log_{10} Reduction	≥ 3.50	≥ 3.50	≥ 3.50	

*Dilution refers to the fold of dilution from the virus inoculum

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51079101	Disinfectant, virucidal	Hard non-porous surface	Spray 6-8 in. from surface; Ready-to-Use	1 minute	5% fetal bovine serum	N/A	• Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)	**Yes**

VI LABEL COMMENTS

Label Date/Identification Number: Version 072420 AMEND

1. The proposed label claim that the product, Condor 2, when applied as a ready to use spray, is an effective disinfectant against Severe Acute Respiratory Syndrome-Related Coronavirus (SARS CoV-2) on visibly clean hard, non-porous surfaces for a 1-minute contact time:

   This claim is **acceptable** as it is supported by the submitted data.

2. Make the following changes to the proposed label:
   a. Throughout the label,
      i. Revise each instance of "Preclean heavily soiled surfaces" to "Preclean visibly soiled surfaces".
      ii. Revise terms such as "fight", "fights", "fighting" bacteria as these terms are misleading regarding the activity of the product. These terms may be revised to "kill" or "effective against" as they are more literal terms.
      iii. When cleaning and disinfection terms are used to describe "one-step" in the same claim, the claim should be qualified to add "when used according to the directions for use for disinfection." The same applies to sanitization and cleaning terms describing "one-step" (i.e., "when used according to the directions for use for sanitization"). The claims that should be revised include, but are not limited to:
         - "Saves money[time][labor][by cleaning and disinfecting in one step]"
         - "Cleans and Sanitizes in One Step"
         - "[Cleans] [and] [disinfects] [in one step]"
      iv. Throughout the label, specifically under sanitization marketing claims on pages 6 and 7, remove "antimicrobial" as a description for sanitization. Sanitization claims were only substantiated by bacterial efficacy data. The term antimicrobial is vague and encompasses other microorganisms beside bacteria.

   b. On page 4, remove "Powered by Microban [antimicrobial] [technology]." This claim implies a heightened efficacy of the product. "Power" or "powerful" cannot be used to describe the efficacy of the product.

   c. On page 6 & 7 under Sanitizing Claims and 24 Hour Residual Sanitizing Claims,
      i. Qualify each instance of "surfaces" to add "hard, nonporous" as a descriptor to accurately reflect the intended type of surfaces for treatment.
      ii. Revise "All-Purpose" to "multi-purpose" in the claim "[Antibacterial][Antimicrobial] All-Purpose Cleaner." Remove "antimicrobial".
      iii. We recommend removing the following claims or revise the language to be similar to "Helps reduce bacteria on hard, nonporous household surfaces for up to 24 hours." The language to "protect/defend/guard surfaces from bacteria" implies heightened efficacy and complete inactivation of bacteria for the indicated exposure time. We recommend using literal terms to not mislead users.
         - "Protects household surfaces from [bacteria] for up to 24 hours"
         - "Protects against bacteria between cleanings for up to 24 hours"

- "Helps you protect treated hard [non porous] surfaces from bacteria for 24 hours"
- "Protects from what you can't see 24 hours of protection [from bacteria growth]*"
- "Protects [treated household surfaces] from bacteria"
- "Protects against bacteria between cleanings"
- "Helps you [protect][defend][guard] your treated surfaces from bacteria"
- "[Surface] protection that lives on for 24 hours"
- "[Microban] Protection that Lives On [for 24 hours]"
- "Sanitize and protect for 24 hours"

iv. Remove brackets from "for up to 24 hours" in the claim "[Patented][Patent Pending] formula [continues to work after multiple touches] [for up to 24 hours]."

v. Remove "…7 day mold and mildew protection]" from the claim "[Provides 24 hour residual antibacterial control] [and] 7 day mold and mildew protection]." Mold and mildew claims should not be listed under sanitization heading.

vi. Remove the statement "bacteria fighting power", "24 Hour Bacteria Shield", and "[This product] [is] the ultimate 24 hour bacteria defender" as these claims imply a heightened efficacy of the product.

d. On page 8,

i. In the statements "[Kills] [Eliminates] [99.9%] bacteria from {insert surface/site from Table 1 or 3}", "[Kills] [Eliminates] [99.9%] bacteria [in] [the] [kitchen] [and] [bathroom]", and "Kills [Eliminates] [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]" remove brackets from "99.9%" when used in conjunction with the term "eliminates" as the original texts imply complete kill.

ii. Add qualifying footnote "§" after "cold and flu viruses" to the statement "Kills 99.9% of SARS-Related Coronavirus 2 [SARS-CoV-2] and cold and flu viruses"

iii. Revise "Helps fight the spread of germs [cold & flu viruses§] [on treated hard nonporous surfaces]" to "Helps reduce the spread of germs [cold & flu viruses§] on treated hard nonporous surfaces." Brackets should be removed from "on treated hard nonporous surfaces."

iv. Add "99.9%" after "Eliminates" in the claim "Eliminates [mold and mildew] [bacteria][viruses†]".

e. On page 9,

i. Revise this statement to remove excess brackets: "[Kills] [Eliminates] [99.9%] [of] [mold and mildew] [bacteria] [viruses†]". In addition, remove brackets from "99.9%" when used in conjunction with the term "eliminates" as this implies complete kill.

ii. Under Fabric Mildewstat Claims as well as under Hard Surface Mildewstat Claims, qualify "fungi", "fungus", and "fungal spores" to add "which cause mildew on fabric articles" or with "nonpathogenic fungi/fungus/fungal spores" to be consistent with the testing method and guidance for this use.

iii. Revise the claim "Protects [Surfaces] from mildew for 28 days* *soft surfaces" to remove "Protects" and to qualify "soft surfaces" to add "with fabric material."

iv. Revise the Emerging Viral Pathogen statements exactly as below to make it easier for users to follow:

"This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses

For an emerging viral pathogen that is an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rotavirus [Strain WA]

Acceptable claim language:

[Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard, non-porous surfaces. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on hard, non-porous surfaces. Refer to the* ***[CDC or OIE]*** *website at* ***[pathogen-specific website address]*** *for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus]. [Product name]*** *kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on hard, non-porous surfaces. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"

f. On page 10, specify fabric material in Table 2: Fabric Mildewstat Use sites/surfaces.

g. On page 15, the graphic that states "Kills 99.9% of Bacteria in 10 Seconds" is limited to hard, non-porous surface sanitization (non-residual) against two bacteria. This graphic should be qualified to indicate this limitation.

Note to PM team: Page 10 lists surface materials (Table 1) that include Copper, Nickel, Zinc, and Tin as these are chemical elements that could react with the product. Please verify for acceptability.